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K023465

510 (k) Summary
[as required by 21 CFR 807.92]

Date Prepared [21 CFR 807.92(a)(1)]

October 14, 2002

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o Kendro Laboratory Products L.P.
P.O. Box 2156
Huntington, CT. 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor Kendro Laboratory Products L.P., 31 Pecks Lane, Newtown, CT 06470.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are: Kendro Laboratory Products HERAcell 240

Common Name: Assisted Reproduction Accessories, Embryo Incubator

Predicate Device [21 CFR 807.92(a)(3)]

- Kendro HERAcell CO_2 Incubator – K002805

There are a few minor differences between the subject device (HERAcell 240) and the predicate device (HERAcell). The differences revolve around the options that are now offered with the HERAcell 240 including Oxygen O_2 control ranges (1-21% for applications requiring hypoxic conditions or a wide range of 5-90%), Infra-red CO_2 Sensor, Roller Bottle System, and the Water Level Alarm.

The predicate device allowed the user to control the Carbon Dioxide levels directly and indirectly control Oxygen and Nitrogen levels by the manipulation of CO2 levels. The subject device allows for the direct control of Carbon Dioxide and Oxygen. The concept of controlling Oxygen levels in incubators is not new. The Forma Scientific Incubator (510k# K991408) allows for the direct control of oxygen levels (2-20%).

Description of the Device [21 CFR 807.92(a)(4)]

The Kendro HERAcell 240 incubators are bench top or floor standing units. The devices control CO_2, temperature, provide elevated humidity, feature a decontamination mode, and control O_2 at suppressed levels to ensure the proper development of ova or embryos at or near body temperature. The conditions produced by the subject device are an exact simulation of physiological conditions. Controlled parameters and alarm functions are microprocessor controlled.

The basic model includes the auto-zero self-balancing CO2 control system, which ensures long term stability of CO2 levels. Each unit is equipped with a water level alarm to remind the user to refill the water reservoir.

As with the predicate device the user has the choice of a stainless steel or solid copper inner chamber. Additionally, the user can choose from additional options such as Oxygen control, Infra-Red Sensor, and the roller bottle system. The basic model includes the TC (thermal conductivity) sensor, however the user can choose the Infra-Red Sensor option.

The main differences between the subject device and the predicate device are related to new options that are offered with the new device as listed below:

- Oxygen O_2 control ranges (1-21% for applications requiring hypoxic conditions or a wide range of 5-90%).
- Infra-red CO_2 Sensor.
- Roller Bottle System (a system with up to 4 bottle turning devices for roller bottles between 58-186mm in diameter).
- Water Level Alarm (included in all HERAcell 240 units)

Intended Use [21 CFR 807.92(a)(5)]

The intended use of this incubator is to provide an environment with controlled temperature, CO_2, elevated humidity, an automatic decontamination mode, and O_2 at suppressed levels, for the development of ova or embryos at or near body temperature.

Technological Characteristics [21 CFR 807.92(a)(6)]

Kendro Laboratory Products L.P. believes that the addition of a few options in the subject device is a minor change from the predicate device. Therefore, it is believed that the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The subject device complies with internationally accepted electrical safety standards as well as other requirements such as CE marking.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

Kendro Laboratory Products, L.P.
% Mr. Joseph M. Azary
Azary Technologies, LLC
P.O. Box 2156
HUNTINGTON CT 06484

Re: K023465
Trade/Device Name: HERAcell 240
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: 85 MQG
Dated: January 18, 2003
Received: January 21, 2003

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5 10(k) Number (if known): K023465

Device Name: Kendro Laboratory Products L.P. HERAcell 240

Indications For Use: The intended use of this incubator is to provide an environment with controlled temperature, CO_2, elevated humidity, an automatic decontamination mode, and O_2 at suppressed levels, for the development of ova or embryos at or near body temperature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023465